

Message

From: Keigwin, Richard [Keigwin.Richard@epa.gov]
Sent: 6/2/2017 11:56:07 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]
CC: Jakob, Avivah [Jakob.Avivah@epa.gov]; Cleland-Hamnett, Wendy [Cleland-Hamnett.Wendy@epa.gov]
Subject: RE: Question on Mosquitos

Sorry for the delay. I had several questions on the materials that were provided. I hope to have something for you by late in the day on Monday (6/5).

From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 6:38 PM
To: Beck, Nancy <beck.nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

I've asked OPP staff to send me some timelines. It may be Friday, given that I was just able to send them a note.

From: Beck, Nancy
Sent: Wednesday, May 31, 2017 2:11 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Ex. 5 - Deliberative Process

Thanks!
Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator, OCSPP
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beck.nancy@epa.gov

From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 4:25 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Depends on the call. I have calls from 6:30am Pacific until 8am Pacific. Then I have a meeting with the Region 9 Acting Regional Administrator and her staff until 10am Pacific. Then I have a call with OGC on a FOIA litigation issue from 9am to 10am Pacific.

Probably a long way of saying, unlikely.

Let me see what I'm hearing.

From: Beck, Nancy
Sent: Wednesday, May 31, 2017 1:22 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Ex. 5 - Deliberative Process

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From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 2:01 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Ex. 5 - Deliberative Process

Leslie Kux is the SES-level point of contact at FDA. She's the Associate Commissioner for Policy. She and I have been keeping in regular contact.

From: Beck, Nancy
Sent: Wednesday, May 31, 2017 10:30 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Rick,
Thank you.
Could an EUP be done in 2 months-assuming we have good data to work with? I'm assuming doing the FR and getting it published is 2 weeks and then a 30 day comment—all while we are reviewing the application.

Who is the POC at FDA we should speak with about the transfer of authority?

Nancy

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From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 10:16 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Ex. 5 - Deliberative Process

From: Beck, Nancy
Sent: Wednesday, May 31, 2017 10:04 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>

Subject: RE: Question on Mosquitos

Rick-

Ex. 5 - Deliberative Process

Thanks!

Nancy B. Beck, Ph.D., DABT
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From: Keigwin, Richard
Sent: Wednesday, May 31, 2017 9:09 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: RE: Question on Mosquitos

Here are some additional details, based upon an interagency meeting that happened a couple of weeks ago between Oxitec, FDA, EPA, and HHS.

Processing Time for an EUP

Under PRIA, the time allotted to complete an EUP review is 7 months. We have committed to issuing the EUP sooner than 7 months after receiving the application, however, how quickly we can complete the review depends, in part, on the completeness of the application. Also, because this would be an experimental use permit of “regional or national significance”, under the regulations we are required to publish a notice of receipt of the EUP application and take comment on the application.

Transfer of Jurisdiction

Based upon the discussion at the interagency meeting with Intrexon/Oxitec, we are of the understanding that the company might be able start mosquito releases sooner under FDA’s jurisdiction because we have determined that we need protein characterization data before moving forward with our review. The group discussed continuing to move forward with plans for a field trial under FDA’s jurisdiction, while simultaneously submitting data to EPA that would support EUP and/or Section 18 assessments needed to allow releases under EPA’s oversight. The company and EPA agreed to expedite the scientific dialogue to get the needed data into EPA as soon as possible.

Oxitec suggested that a viable path would be where testing with field trials could occur under FDA oversight during the Summer/Fall of 2017 with an EPA EUP submission sometime in the Fall of 2017 and EUP issuance (and transfer of jurisdiction) occurring in February 2018 for field trial oversight in the Spring/Summer 2018 under an EPA EUP.

Section 3 Review Time

Under PRIA, the review time is approximately 13 months. This would include two comment periods: one upon receipt of the section 3 application and one at the end where we would propose a registration decision. I've been talking with the division director about whether we would need to have an SAP review before we completed our evaluation or after. With the plant-incorporated protectants, we have not had an SAP review prior to registration. For the Wolbachia mosquito that we will soon be proposing to register (hopefully this week), there has not been an SAP review. As with the EUP timeframe, in part, the timeframe depends upon the completeness of the application. Oxitec is preparing a crosswalk between the data they currently have available with our data requirements. Other than the protein characterization date, the efficacy data could be an issue. For Wolbachia, we are proposing to geographically restrict the registration, tailored the allowed use areas to match with the conditions under which the efficacy data were generated.

As always, let me know if you have any additional questions.

From: Beck, Nancy

Sent: Tuesday, May 30, 2017 2:42 PM

To: Keigwin, Richard <Keigwin.Richard@epa.gov>

Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>

Subject: Question on Mosquitos

Rick,

A few questions:

- 1) Are we closing the loop with FDA to see if they have any uses that would be interrupted by a transfer of authority to EPA? Is this something we should ask OGC to find out about or do you have the connections?
- 2) If oxitec were to submit an EUP, about how long do you think review would take? Oxitec says they heard 1 month then 7 months.
- 3) If oxitec were to submit a Section 3, for a conditional approval, about how long do you think review would take?

And of course, I understand that these are just estimates and it would depend on what they send us. Oxitec is saying that your folks have familiarity with the data from working with FDA on the issue.

Thanks!

Nancy

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